



## **MedinCell announces filing of its *document de base* with the AMF, the first step towards its planned IPO on the regulated market of Euronext in Paris**

**Jacou, France, September 5, 2018, 9.00 am CEST** - MedinCell, a technological pharmaceutical company that develops a portfolio of long-acting injectable products in various therapeutic areas, today announces the registration of its *document de base* with the *Autorité des marchés financiers* (“AMF”, the French Financial Markets Authority) under number I.18-062 on September 4, 2018. This is the first step towards MedinCell’s planned initial public offering (“IPO”) on the regulated market of Euronext in Paris, subject to market conditions and to receiving the AMF’s visa on the IPO prospectus.

With its 110 employees, MedinCell’s objective is to significantly improve the efficiency of medical treatments. Amongst its products in development, the two most advanced – which address the treatment of schizophrenia and postoperative orthopaedic pain – are respectively in a Phase III and Phase II clinical trial in the United States. Its seven other ongoing programmes target various therapeutic areas (depression, chronic pain, contraception, etc.) in which its BEPO® patented technology could be a game changer.

The long-acting injectable products developed by MedinCell combine active pharmaceutical ingredients present in already marketed drugs (of which the efficacy and safety profile are known and documented) with its BEPO® technology. They thus allow to combine the relatively low risk associated with the reformulation of an existing drug and the significant market potential of a new treatment.

Within the framework of the development and manufacturing of its products, MedinCell collaborates with leading partners such as Teva Pharmaceuticals, AIC<sup>1</sup>, the Bill & Melinda Gates Foundation and Corbion, one of the largest global manufacturers and suppliers of biopolymers for the pharmaceutical industry.

*“Our team is proud to have reached this new milestone that is a natural extension of what we have already built to take MedinCell to an advanced stage of maturity”, says **Christophe Douat, Chairman of MedinCell’s Executive Board**. “We have proven our know-how, our ability to drive our projects forward and the potential of our technology, with a first product in the final phase of clinical trials prior to its marketing in the United States and a growing number of programmes in development. The compatibility of our BEPO® technology with numerous active pharmaceutical ingredients, combined with MedinCell’s expertise in formulation, enables us to envisage the broadening of our portfolio in a number of indications to address currently unmet needs in developed and emerging countries.”*

### **BEPO®: a technology with substantial potential for long-acting injectable treatments**

The proprietary BEPO® technology allows the controlled release of an active pharmaceutical ingredient over a targeted period of days, weeks or months via a simple subcutaneous injection for a systemic action, or a local injection for a targeted action. Through the injection, the BEPO® technology forms a polymer depot measuring only a few millimetres that releases the active ingredient, and totally disappears after resorption.

The long-acting subcutaneous injection is an alternative to traditional – often oral – drug-taking methods. It aims to enhance treatments’ efficiency by improving adherence with medical prescriptions, a major and global issue. Indeed the World Health Organisation (WHO) estimates that one in two patients either

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<sup>1</sup> Arthritis Innovation Corporation: a company founded by North American clinicians and entrepreneurs

does not begin or fail to follow their treatment and that “an improvement in adherence would have more impact than any improvement in medical treatment”<sup>2</sup>.

A long-acting and local injection enables the direct administration of an active pharmaceutical ingredient to the targeted area, via an intra-articular or perineural injection for example, especially in the context of a surgical procedure. The objective is to significantly reduce the quantity of drugs compared with the quantity needed if administered orally or intravenously to achieve the same effect, while limiting adverse effects.

### An attractive risk-return profile related to the reformulation of existing drugs and to the improvement of their efficiency

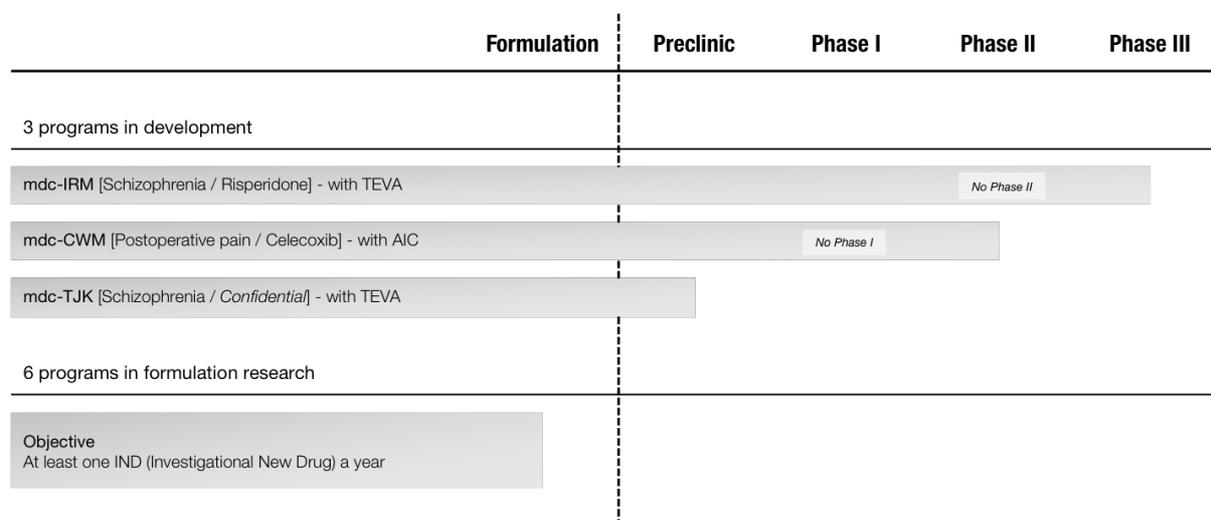
The products currently being developed by MedinCell use active pharmaceutical ingredients that are present in drugs already available on the market. Associated development costs and timeframes can therefore be reduced. This category of products therefore makes it possible to combine the lower risk of reformulating a known drug, versus a new molecule, with the commercial potential of a new drug thanks to the treatment’s enhanced efficiency compared to its existing forms.

### An extensive and diversified portfolio at an advanced stage of development and targeting major therapeutic issues

MedinCell’s portfolio currently includes three products in clinical or preclinical phases and six at the formulation research stage. Moreover, MedinCell is aiming to file at least one new IND (Investigational New Drug) per year.

MedinCell’s IPO project is intended to enable it to acquire the financial capacity needed to develop this portfolio and, to a limited extent, to refinance part of its debt.

The three products having passed the formulation research stage and currently in development are:



- **mdc-IRM**, currently in a Phase III clinical trial in the United States for the treatment of schizophrenia, in partnership with the international pharmaceutical group Teva. mdc-IRM is developed from an atypical antipsychotic commonly used for the treatment of this disorder, Risperidone. Schizophrenia, indication for which adherence is a major issue, affects more than 23 million people worldwide, represents 20% of the total number of days of hospitalisation in the United States<sup>3</sup> and an estimated

<sup>2</sup> Adherence to Long-Term Therapies, Evidence for Actions (2003)

<sup>3</sup> Comprehensive understanding of schizophrenia and its treatment, Maguire GA: <https://www.ncbi.nlm.nih.gov/pubmed/12227084>

annual economic loss of between \$134.4 billion and \$174.3 billion<sup>4</sup>. The long-acting injectable antipsychotic market was worth \$4.4 billion in 2017, with annual growth of 20%<sup>5</sup>.

- **mdc-CWM**, currently in a Phase II clinical trial in the United States for the treatment of orthopaedic postoperative pain and inflammation, in partnership with AIC, a company specialising in orthopaedic surgery. It is a new anti-inflammatory formulation, injected intra-articularly when a knee prosthesis is implanted, that aims to considerably reduce postoperative pain and inflammation and to reduce opioid use. The efficacy of existing treatments remains limited, since 57% to 73% of operated patients express that they suffer from moderate to extreme postoperative pain<sup>6</sup>. In the United States, opioid addiction, which can follow prescribed postoperative use, has reached epidemic proportions in recent years. The Centers for Disease Control and Prevention (CDC) estimates that 91 people die every day in the United States from an opioid overdose.
- **mdc-TJK**, currently in preclinical development for the treatment of schizophrenia. This product, also developed in partnership with Teva, is based on a molecule different than Risperidone, and could target other patients than those of mdc-IRM.

Furthermore, MedinCell is supported by the Bill & Melinda Gates Foundation in a formulation research programme that aims to develop a 6-month injectable contraceptive that could notably facilitate women's access to contraception in developing countries. MedinCell's portfolio also includes five other formulation research programmes in therapeutic areas such as the central nervous system, pain and organ transplants, including a third product developed in partnership with Teva.

Availability of the *document de base*: MedinCell's *document de base* is available on the Company's website ([investors.medincell.com](http://investors.medincell.com)) and the AMF website ([www.amf-france.org](http://www.amf-france.org)), as well as free of charge upon request from the Company's head office, 3 Rue des Frères Lumière, 34830 Jacou, France. The Company draws your attention to Chapter 4, "Risk Factors", of the *document de base* registered with the AMF on September 4, 2018 under number I.18-062.

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## About MedinCell

MedinCell is a pharmaceutical company that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO<sup>®</sup> technology with active ingredients already known and marketed. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved adherence, i.e. adherence with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. The BEPO<sup>®</sup> technology allows to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple depot of a few millimetres, fully bioresorbable. Based in Montpellier, MedinCell currently employs approximately 100 people representing over 25 different nationalities.

[www.medincell.com](http://www.medincell.com)

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<sup>4</sup> The Economic burden of schizophrenia in the United States in 2013, Analysis Group, Otsuka, Lundbeck LLC – 2016:  
<https://www.ncbi.nlm.nih.gov/pubmed/27135986>

<sup>5</sup> IMS sales data - MIDAS

<sup>6</sup> Gan TJ, Habib AS, Miller TE, White W, Apfelbaum JL. Incidence, patient satisfaction, and perceptions of post-surgical pain: Results from a US national survey. *Curr Med Res Opin.* 2014;30(1):149-160

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## **Forward-looking Statements**

This press release may contain forward-looking statements. These statements do not constitute guarantees regarding the future performance of MedinCell. This forward-looking information covers the future outlook, growth and commercial strategy of MedinCell and is based on the analysis of future result forecasts and estimates of amounts that cannot yet be determined. By nature, forward-looking information involves risks and uncertainties, as it relates to events and depends on circumstances that may or may not occur in the future. MedinCell draws your attention to the fact that forward-looking statements provide no guarantee of future performance and that its actual financial position, results and cash flow, as well as changes in the sector in which MedinCell operates, may differ significantly from those proposed or suggested by the forward-looking statements contained in this document. Moreover, even if MedinCell's financial position, results, cash flow and changes in the sector in which MedinCell operates were to be in accordance with the forward-looking information contained in this document, these results or changes may not be a reliable indicator of MedinCell's future results or developments. A description of events that could have a material adverse impact on MedinCell's business, financial position or results, or on its ability to achieve its targets, is given in Chapter 4 "Risk Factors" of the Document de base.

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No communication or other information related to this transaction or to MedinCell may be transmitted to the public in a country in which any approval or registration is required. No steps to such end have been taken or will be taken by the Company in any country in which such steps would be required (other than France).

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